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Examiner: David Isabella
Art Unit: 3738

REMARKS

While the Examiner and Attorney for Applicant had previously discussed the claims in an Interview and it was agreed that all claims were allowable over the prior art of record, the Examiner has determined that he may have not fully appreciated the issues surrounding the limitations of a "spring-loaded" bucket handle. The Attorney for Applicant provides the following additional remarks which he believes will help the Examiner understand how the claimed prosthesis is patentably distinguished from the prosthesis described in Shea in light of the present claim language. The Examiner's open consideration of the arguments presented is appreciated.

Claims 14-18, 29-39 and 41 are allowed.

Claims 1 and 4-7 stand rejected under 35 U.S.C. § 102(b) as anticipated by Shea (U.S. Pat. No. 4,292,693). The rejection is traversed for the following reasons. Shea teaches a bucket handle prosthesis with a stainless steel handle which is locked relative to the bucket with two cam locks. The Applicant's invention is directed to a bucket handle prosthesis having a spring loaded handle by which it is coupled to the bucket. The Examiner states that he has looked to the specification for the metes and bounds of the term "spring loaded" and has directed attention to page 24, line 8 – page 25, line 1+. Then he states, "**based on this sole disclosure**, examiner maintains that the steps outlined in applicant's specification do not distinguish over the same steps disclosed in Shea." However, the portion of the disclosure referenced by the Examiner is but a small portion

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of the disclosure in the specification related to the spring loaded bail and unfortunately the Examiner has not fully determined the metes and bounds as he set out to do.

The Examiner is directed to page 20, lines 5-9:

The handle 104 has end portions 118, 120 which are inwardly directed toward each other and define a space therebetween that is smaller than the outer diameter of the bucket 106 at the bail insert openings 110, 112.

That is the space between the ends of the handle is smaller than bucket diameter. Then, at page 20, line 18 – page 21, line 12:

The properties of titanium, as the preferred material for the handle, contribute in several areas with respect to the prosthesis 100. Since titanium has better spring-like mechanical properties than stainless steel, this characteristic can be used to hold the handle 104 to the bucket 106 of the prosthesis, e.g., the spring-like tension forces the ends 118, 120 of the handle 104 into the bail insert openings 110, 112, thus holding the handle 104 to the bucket 106 without the need for welding, twisting or crimping. The ends 118, 120 of the bail handle 104 are not coupled to each other, do not contact each other, and do not pass each other within the bucket 106. And once manipulated by the surgeon, the bail handle 104 under tension remains in a fixed relationship relative to the bucket 106 without concern of unintended movement which may otherwise result in undesirable loosening of the incus relative to the prosthesis 100.

Thus, the ends of the handle are spread apart and placed under tension when inserted into the bail insert openings, as the bail insert openings are displaced at a greater dimension than the space between the ends. Also, at page 21, lines 18-21:

During the assembly process, the ends 118, 120 of the handle 104 are slightly spread apart, manipulated about the bucket 106 and then released into the bail insert openings 110, 112 of the bucket 106 of the prosthesis, a much simpler method than current approaches.

Additional teaching is provided at page 13, line 15 – page 14, line 12. As such, it is clear from the specification that “spring-like” and “under tension” (i.e., “spring loaded”) refer

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to the manner in which the bail handle ends couple relative to the bucket. This is made possible by both the dimension of the bail handle at the bail handle openings and the material property of the bail handle.

The Examiner contends that the language in Shea at certain locations in the description indicates that the bail thereof is sufficiently resilient to meet the limitations of 'spring loaded' as claimed. However, once the metes and bounds of "spring loaded" has been fully and properly considered (i.e., not simply that the handle is comprised of a resilient material, but rather how that handle is functionally coupled to the bucket as described above); i.e., that such resilient material is spring-loaded, there is no teaching or suggestion in Shea for such a construct. That is, it is necessary that the limitation be read not as simply requiring a spring material for the handle, but rather that the handle is **spring-loaded**.

Furthermore, with respect to claims 4 and 7, the bail handle in the present case is **U-shaped**. See Fig. 7, element 104. In distinction, the handle of Shea has its ends permanently joined together at weld 38 (Fig. 7, Shea). Thus, it is clearly not a U-shaped handle, but rather a **D-shaped** handle. Moreover, contrary to the handle of the invention, the ends of the handle of Shea are **not received** in the holes of the bucket **under any** load.

In view of the foregoing, claim 1 and all claims dependent thereon are allowable over Shea.

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Claims 27 and 28 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Shea as applied to claim 1 in view of Beyer (U.S. Pat. No. 2,792,958) or Kulbacki (U.S. Pat. No. 3,593,880). The rejection is traversed for at least the following three reasons.

First, for the reasons, presented above with respect to claim 1, claims 27 and 28 are allowed.

Second, both the secondary references cited by the Examiner come from non-analogous art. To rely on a reference under 35 U.S.C. § 103, the reference must be analogous art. MPEP 2141.01(a). "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." In re Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). Beyer pertains to a container handle for 'gallon' size bottle such as for milk, while Kulbacki is directed to a paint brush support. Neither reference is in the field of applicant's endeavor. The problem, broadly speaking, to which both applicant and Shea were concerned was how to anchor an element (the incus) within a bucket to which the handle is attached. Neither of the secondary references is related to anchoring an element in a bucket to which the handle is attached. Therefore, the references are clearly non-analogous art and are not properly combinable with Shea.

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Third, Shea teaches a handle having ends which are joined and located within the body. The secondary references teach a handle (Beyer) or support (Kulbacki) which has ends which are detached but not located within the body. In Beyer, the handle ends are captured in portions of a band 4 and do not enter the container. In Kulbacki, the support ends are attached to bosses coupled to the surfaces of the body and do not extend within the body. In Beyer, the Even if the art were analogous, the teachings are irreconcilable. For the foregoing reasons, claims 27 and 28 are allowable over the cited art.

Claims 1, 3-7, 9-13, 27-28 and 51 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Shea in view of U.S. Pat. No. 6,726,719 to Antonelli. The applicant respectfully traverses the rejection for the following reasons.

First, for the reasons advanced above with respect to claim 1, 4 and 7 with respect to Shea, it is submitted that the claims are allowable.

Second, while Antonelli does teach that titanium may be used for its spring-like quality in the otic art, there is no suggestion in the art that the bucket handle of a stapedial prosthesis, which functions differently than the structure in Antonelli, should be "spring-loaded" or made of "titanium". More particularly, in the claimed invention the bucket supports and engages the process of the incus and the claimed handle prevents release of the process with its spring-load facilitating maintaining its position on the process once so placed by the surgeon. However, the force of the spring-loaded handle is not applied directly to the process but rather to the bucket. In distinction, in Antonelli the titanium

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jaws operate to actually support and engage the process of the incus, with the force of the spring 28 acting directly on the jaws and thus the process. There is no secondary feature which corresponds to the handle. Furthermore, Shea provides other structure, cams 36 which are intended to lock the handle and therefore obviate the need for creating the tension of the spring-loaded handle of the invention. As such, the teaching of the Antonelli does not appropriately give incentive to modify the bucket handle of Shea so as to make it from titanium or under a spring load. Given the Shea and Antonelli references, no one skilled in the art would look at the references and find that they suggest the invention as claimed.

Further, claim 9 has been amended to include that the handle is coupled under "spring tension" to the bucket. For reasons advanced above in the discussed with respect to claim 1, this is not suggested by Shea.

With respect to claims 27 and 28, the Examiner again states that "the language of the claim does not preclude the intermediate product where the first and second ends are not coupled." However, the teaching of Shea specifically teaches away from an intermediate product that reads on the claimed invention. Referring to col. 4, lines 33-40, Shea states:

[B]ail 18 is preferably formed of a single strand of wire with its ends joined in butting relationship as by weld 38. *The material of bail 18 is such that one end may be deformed and inserted completely through bore 28 so that weld 38 may be made; thereafter weld 38 is pulled into bore 28 until it is approximately centered and the deformed portion resumes its original shape. (emphasis added)*